United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-016 April 1995

R.E.D. FACTS

Dowicil®CTAC

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3069, Dowicil®CTAC.

Use Profile

Dowicil®CTAC is used as a microbicide/microbistat for secondary oil injection water-water treatment and as a preservative for industrial adhesives and coatings; resin/latex/polymer emulsions; metalworking cutting fluids; oil recovery drilling muds/packer fluids; latex(in-can) paints; specialty industrial products; textiles/textile fibers/cordage; and wet-end additives/industrial processing chemicals.

The case Dowicil®CTAC contains the two active ingredients Dowicil®75 and Dowicil®150. The active ingredient Dowicil®75 contains both the cis-(.53%) and the trans-(.44%) isomers of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. The active ingredient Dowicil®150 contains only the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.

Regulatory History

A pesticide product containing Dowicil®150 was first registered in the United States in 1964 as a microbicide/microbistat. A second registration, for Dowicil®75, was granted in 1972 for use as a preservative for paints, latexes, metalworking lubricants, and other industrial formulations to prevent deterioration from bacteria and fungi.

The food additive use of Dowicil®CTAC to preserve adhesives, resins, pulp, and paperboard that contact foods is regulated by the Food and Drug Administration (please see 21 CFR Sections 175.105, 176.1680, 176.170, and 176.180).

In 1987, EPA issued the Antimicrobial Data Call-In (DCI) Notice to obtain chronic and subchronic toxicity data for Dowicil®CTAC and other antimicrobials. The Agency issued a second DCI under reregistration Phase 4 in March 1992, requiring the registrant to provide chemistry, toxicology, and environmental fate data on these active ingredients to support reregistration.

Human Health Assessment

Toxicity

In laboratory animal studies measuring acute toxicity, technical grade Dowicil®CTAC has been shown to cause moderate effects by the dermal route, placing it in Toxicity Category II (the second-highest of four categories) for dermal toxicity. It has been shown to produce slight irritation in eye and dermal irritation studies, placing it in Toxicity Category III for eye irritation and Toxicity Category IV for skin irritation. It is slightly toxic in oral toxicity studies, placing it in Toxicity Category III for oral toxicity. In an acute inhalation study, Dowicil®CTAC was found to be slightly toxic, placing it in Toxicity Category IV. This chemical is not a skin sensitizer based on studies using guinea pigs.

A 90-day dermal toxicity study in rabbits established the NOEL for systemic toxicity as 1000 mg/kg/day.

Dowicil®CTAC was mutagenic in the in vitro Chinese hamster ovary cell HGPRT forward mutation assay with activation, but was nonmutagenic without activation. It was negative in two other mutagenicity studies.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of Dowicil®CTAC since no food or feed uses are registered.

Occupational and Residential Exposure

Due to its low toxicity and the lack of a toxicological endpoint of concern, an exposure assessment was not required for Dowicil®CTAC. However, formaldehyde is released when Dowicil®CTAC decomposes in aqueous solution. EPA is concerned because formaldehyde has been classified as a Group B1 "probable human carcinogen."

The potential for exposure to Dowicil®CTAC and/or formaldehyde exists for occupational workers involved in the industrial setting and for individuals in the home setting. For residential uses, the Agency has determined that potential exposure to Dowicil®CTAC is minimal. For industrial uses, most workers' exposure to Dowicil®CTAC is low because of current use patterns. In addition, workers in industrial settings are protected by the Occupational Safety and Health Administration's (OSHA's) comprehensive workplace standard for formaldehyde, with a permissible

exposure level (PEL) of .75 ppm in the workplace. EPA has notified OSHA of Dowicil®CTAC's potential to release formaldehyde and OSHA has agreed to include these products in their workplace monitoring program.

Since Dowicil®CTAC causes moderate acute dermal toxicity (Toxicity Category II), EPA is requiring that labels contain a statement advising workers to wear chemical resistant gloves for open-pouring of the end-use product.

Human Risk Assessment

Since Dowicil®CTAC has no food or feed uses, dietary risk is not expected. The chemical causes moderate acute dermal toxicity. Therefore, to protect applicators' skin during open pouring of end-use products, EPA is requiring appropriate label precautions regarding use of protective clothing (chemical resistant gloves). Although Dowicil®CTAC releases formaldehyde in aqueous solutions, minimal risk is expected in residential settings. Occupational risks are low due to the chemical's use pattern and because OSHA will monitor workers' exposure to formaldehyde during industrial uses of Dowicil®CTAC. No human health risk of concern is therefore expected.

Environmental Assessment

Environmental Fate

Dowicil®CTAC dissipates by abiotic hydrolysis. It is not persistent and degrades rapidly under acidic conditions. Under neutral to alkaline conditions, it degrades more slowly.

Ecological Effects

Both Dowicil®75 and Dowicil®150 are practically nontoxic to slightly toxic to birds, fish, aquatic invertebrates, and terrestrial animals.

Ecological Effects Risk Assessment

The use patterns of Dowicil®CTAC result in minimal risk to terrestrial organisms. Risk to nontarget aquatic organisms can be expected through point source discharge of industrial microbicides. In the case of Dowicil®CTAC, there are several use sites and environmental conditions where exposure to aquatic organisms is a distinct possibility.

Based on Agency calculations using an exposure model, the chronic level of concern (LOC) for aquatic species is exceeded in both typical and high exposure scenarios for wet-end additives/industrial processing chemicals and oil recovery drilling muds/packer fluids. The acute LOC is exceeded in high exposure scenarios for all five use patterns examined. Endangered aquatic species also are at risk under both typical and high exposure scenarios.

It is important to note, however, that the Agency's calculations likely overestimate the actual concentrations which would be found in the environment. Also, discharge levels are governed by NPDES permits granted by state regulatory agencies and EPA. Based on its rapid hydrolysis

and use sites, no additional environmental fate date are required for Dowicil®CTAC.

Additional Data Required

EPA is requiring product-specific data including product chemistry and efficacy data, revised Confidential Statements of Formula (CSFs), and revised product labeling for reregistration of products containing Dowicil®CTAC.

Product Labeling Changes Required

The labels of all registered pesticide products containing Dowicil®CTAC must comply with EPA's current pesticide labeling requirements. In addition:

Effluent Discharge Statement - All end-use (and manufacturing use) products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following statement:

> "This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of the National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

Handler PPE for Occupational-Use Products - The minimum (baseline) personal protective equipment (PPE) for handlers engaged in open pouring of Dowicil®75 and Dowicil®150 is chemical-resistant gloves.

Regulatory Conclusion

The use of currently registered pesticide products containing Dowicil®CTAC in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These Dowicil®CTAC products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for Dowicil®CTAC during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at

703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the Dowicil®CTAC RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the Dowicil®CTAC RED, or reregistration of individual products containing Dowicil®CTAC, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.